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*Committee on the Environment, Public Health and Food Safety  
Committee on Agriculture and Rural Development*

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**2013/0433(COD)**

23.3.2015

**\*\*\*I**

## **DRAFT REPORT**

on the proposal for a directive of the European Parliament and of the Council  
on the cloning of animals of the bovine, porcine, ovine, caprine and equine  
species kept and reproduced for farming purposes  
(COM(2013)892 – C7-0002/2014 – 2013/0433(COD))

Committee on the Environment, Public Health and Food Safety  
Committee on Agriculture and Rural Development

Rapporteurs: Renate Sommer, Giulia Moi

(Joint committee meetings – Rule 55 of the Rules of Procedure)

### ***Symbols for procedures***

- \* Consultation procedure
- \*\*\* Consent procedure
- \*\*\*I Ordinary legislative procedure (first reading)
- \*\*\*II Ordinary legislative procedure (second reading)
- \*\*\*III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

### ***Amendments to a draft act***

#### **Amendments by Parliament set out in two columns**

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

#### **Amendments by Parliament in the form of a consolidated text**

New text is highlighted in ***bold italics***. Deletions are indicated using either the ■ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.

By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

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## DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

**on the proposal for a directive of the European Parliament and of the Council on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes**

**(COM(2013)892 – C7-0002/2014 – 2013/0433(COD))**

**(Ordinary legislative procedure: first reading)**

*The European Parliament,*

- having regard to the Commission proposal to Parliament and the Council (COM(2013)892),
  - having regard to Article 294(2) and Article 43(2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0002/2014),
  - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
  - having regard to the opinion of the European Economic and Social Committee of 30 April 2014<sup>1</sup>,
  - having regard to Rule 59 of its Rules of Procedure,
  - having regard to the joint deliberations of the Committee on the Environment, Public Health and Food Safety and the Committee on Agriculture and Rural Development under Rule 55 of the Rules of Procedure,
  - having regard to the report of the Committee on the Environment, Public Health and Food Safety and the Committee on Agriculture and Rural Development and the opinion of the Committee on International Trade (A8-0000/2015),
1. Adopts its position at first reading hereinafter set out;
  2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
  3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

### **Amendment 1**

**Proposal for a directive**  
**Title**

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<sup>1</sup> OJ C311, 12.9.2014, p.73-81.

*Text proposed by the Commission*

Proposal for a **Directive** of the European Parliament and the Council on the cloning of animals ***of the bovine, porcine, ovine, caprine and equine species*** kept and reproduced for farming purposes

*Amendment*

Proposal for a **Regulation** of the European Parliament and the Council on the cloning of animals kept and reproduced for farming purposes

*(The first part of this amendment, namely the change from Directive to Regulation, applies throughout the text. Adopting it will necessitate corresponding changes throughout.)*

Or. en

**Amendment 2**

**Proposal for a directive**  
**Recital 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***(2a) The European Group on Ethics in Science and New Technologies (EGE) in its specific report on cloning in 2005<sup>1a</sup> expressed doubts that animal cloning for food production purposes can be justified “considering the current level of suffering and health problems of surrogate dams and animal clones”.***

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<sup>1a</sup> ***Ethical aspects of animal cloning for food supply 16 January 2008:***  
***[http://ec.europa.eu/bepa/european-group-ethics/docs/publications/opinion23\\_en.pdf](http://ec.europa.eu/bepa/european-group-ethics/docs/publications/opinion23_en.pdf)***

Or. en

**Amendment 3**

**Proposal for a directive**  
**Recital 2 b (new)**

*Text proposed by the Commission*

*Amendment*

***(2b) One of the objectives of the Union’s common agriculture policy enshrined in Article 39 of the Treaty on the Functioning of the European Union (TFEU) is the “increase of agricultural productivity by promoting technical progress and by ensuring the rational development of agricultural production”. That objective aims, inter alia, at improving production, and with regard to the rational development of agricultural production, it entails the optimum utilisation of the factors of production, namely appropriate production for marketing purposes that takes into account the interests of consumers.***

Or. en

#### **Amendment 4**

##### **Proposal for a directive Recital 2 c (new)**

*Text proposed by the Commission*

*Amendment*

***(2c) According to case-law<sup>1a</sup> of the Court of Justice of the European Union, Article 43 TFEU is the appropriate legal basis for any legislation concerning the production and marketing of agricultural products listed in Annex I TFEU which contributes to the achievement of one or more of the objectives of the common agricultural policy set out in Article 39 TFEU. Even where such legislation could be directed to objectives other than those of the common agricultural policy, which, in the absence of specific provisions, would be pursued on the basis of Article 114 TFEU, it may involve the harmonisation of provisions of national law in that area***

*without recourse to Article 114 being necessary. Furthermore, measures taken in the context of the common agricultural policy may also affect importation of the products concerned.*

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*<sup>1a</sup> Cases 68/86 United Kingdom of Great Britain and Northern Ireland v Council of the European Communities [1988] ECR 855; C-11/88 Commission of the European Communities v Council of the European Communities [1989] ECR 3799; C-131/87 Commission of the European Communities v Council of the European Communities [1989] ECR 3743.*

Or. en

## Amendment 5

### Proposal for a directive Recital 3

#### *Text proposed by the Commission*

(3) Taking into account the objectives of the Union's agricultural policy, the results of the recent *scientific* assessments of EFSA and the animal welfare requirement provided in Article 13 *of the Treaty*, it is prudent to *provisionally* prohibit the use of cloning in animal production for *farm* purposes *of certain species*.

#### *Amendment*

(3) Taking into account the objectives of the Union's *common* agricultural policy, the results of the recent assessments of EFSA, *based on all available scientific studies*, and the animal welfare requirement provided in Article 13 *TFEU*, it is prudent to prohibit the use of cloning in animal production for *farming* purposes.

Or. en

## Amendment 6

### Proposal for a directive Recital 4

*Text proposed by the Commission*

*Amendment*

***(4) Currently animals of bovine, porcine, ovine, caprine and equine species are likely to be cloned for farming purposes. The scope of this Directive should therefore be limited to the use of cloning for farming purposes of those five species.***

***deleted***

Or. en

## **Amendment 7**

### **Proposal for a directive Recital 4 a (new)**

*Text proposed by the Commission*

*Amendment*

***(4a) The majority of Union citizens disapprove of cloning for farming purposes due to, inter alia, animal welfare and general ethical concerns. Cloning for farming purposes could lead to animal clones or the descendants of animal clones entering the food chain. Consumers do not want to consume food from animal clones or their descendants.***

Or. en

## **Amendment 8**

### **Proposal for a directive Recital 4 b (new)**

*Text proposed by the Commission*

*Amendment*

***(4b) With regard to marketing of agricultural products, as a consequence of prohibiting the use of cloning and in order to address consumer perceptions on***

*cloning linked to, inter alia, animal welfare and general ethical concerns it is necessary to ensure that food from animal clones and their descendants does not enter the food chain. Less restrictive measures, such as food labelling, would not entirely address citizens' concerns since the marketing of food produced with a technique that implies animal suffering would still be allowed.*

Or. en

## Amendment 9

### Proposal for a directive Recital 4 c (new)

*Text proposed by the Commission*

*Amendment*

*(4c) The use of cloning in animal production for farming purposes is allowed in certain third countries. Pursuant to Regulation (EC) No 178/2002 of the European Parliament and of the Council<sup>1a</sup>, food imported from third countries for placing on the market within the Union is to comply with Union relevant requirements of food law or with conditions recognised by the Union to be at least equivalent to those requirements. Therefore, measures should be taken to avoid the import into the Union of food obtained from animal clones and their descendants produced in third countries.*

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<sup>1a</sup> *Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).*

## Amendment 10

### Proposal for a directive Recital 4 d (new)

*Text proposed by the Commission*

*Amendment*

***(4d) The application of this Regulation can be jeopardised where it is impossible to trace food obtained from animal clones and their descendants. Therefore, pursuant to the precautionary principle and in order to enforce the prohibitions set out in this Regulation, it is necessary to establish, in consultation with the relevant stakeholders, traceability systems at Union level. Such systems would enable competent authorities and economic operators to collect data on animal clones, descendants of animal clones and germinal products of animal clones and of their descendants, and food from animal clones and their descendants.***

Or. en

## Amendment 11

### Proposal for a directive Recital 5

*Text proposed by the Commission*

*Amendment*

***(5) It is expected that the knowledge on the impact of the cloning technique on the welfare of the animals used will increase. The cloning technique is likely to improve over time. Consequently prohibitions should only apply provisionally. This Directive should therefore be reviewed within a reasonable time taking into***

***(5) This Regulation should be reviewed within a reasonable time, taking into account the experience gained by the Member States in its application, scientific and technical progress, the evolution of consumer perceptions, and international developments.***

account the experience gained by the Member States in its **implementation**, scientific and technical progress and international developments.

Or. en

## Amendment 12

### Proposal for a directive Recital 5 a (new)

*Text proposed by the Commission*

*Amendment*

***(5a) The power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the establishment of rules for traceability systems for animal clones, descendants of animal clones and for germinal products of animal clones and of their descendants. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.***

Or. en

## Amendment 13

### Proposal for a directive Recital 6

*Text proposed by the Commission*

*Amendment*

(6) This **Directive** respects the fundamental

(6) This **Regulation** respects the

rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union, and *notably* the freedom to conduct a business and the freedom of the sciences. This *Directive* has to be *implemented* in accordance with these rights and principles.

fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union, and *in particular* the freedom to conduct a business and the freedom of the sciences. This *Regulation* has to be *applied* in accordance with these rights and principles.

Or. en

#### Amendment 14

##### Proposal for a directive Recital 6 a (new)

*Text proposed by the Commission*

*Amendment*

***(6a) Since the objective of this Regulation cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.***

Or. en

#### Amendment 15

##### Proposal for a directive Article 1 – paragraph 1 – point b

*Text proposed by the Commission*

*Amendment*

(b) the placing on the market of *embryo*

(b) the placing on the market *and import* of

*clones and* animal clones.

animal clones, *embryo clones, descendants of animal clones, germinal products of animal clones and of their descendants, and food from animal clones and their descendants.*

Or. en

## Amendment 16

### Proposal for a directive Article 1 – paragraph 2

*Text proposed by the Commission*

It shall apply to animals *of the bovine, porcine, ovine, caprine and equine species ('the animals')* kept and reproduced for farming purposes.

*Amendment*

It shall apply to animals kept and reproduced for farming purposes.

Or. en

## Amendment 17

### Proposal for a directive Article 2 – paragraph 1 – point a

*Text proposed by the Commission*

(a) animals “kept and reproduced for farming purposes” means animals kept and reproduced for the production of food, wool, skin or fur or for other farming purposes. It shall not include animals kept and reproduced exclusively for other purposes such as research, the production of medicinal products and medical devices, the preservation of rare breeds or endangered species, *sporting and cultural events*;

*Amendment*

(a) “animals kept and reproduced for farming purposes” (*“the animals”*) means animals kept and reproduced for the production of food, wool, skin or fur or for other farming purposes. It shall not include animals kept and reproduced exclusively for other purposes such as research, the production of medicinal products and medical devices, *or* the preservation of rare breeds or endangered species;

Or. en

## Amendment 18

### Proposal for a directive Article 2 – paragraph 1 – point b a (new)

*Text proposed by the Commission*

*Amendment*

***(ba) “descendants of animal clones” means animals, other than animal clones, where at least one of the progenitors is an animal clone;***

Or. en

## Amendment 19

### Proposal for a directive Article 2 – paragraph 1 – point b b (new)

*Text proposed by the Commission*

*Amendment*

***(bb) “germinal products” means semen, oocytes and embryos collected or produced from animals for the purpose of reproduction;***

Or. en

## Amendment 20

### Proposal for a directive Article 2 – paragraph 1 – point b c (new)

*Text proposed by the Commission*

*Amendment*

***(bc) “traceability” means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of***

*production, processing and distribution;*

Or. en

#### **Amendment 21**

##### **Proposal for a directive**

##### **Article 2 – paragraph 1 – point c a (new)**

*Text proposed by the Commission*

*Amendment*

*(ca) “food” means food as defined in Article 2 of Regulation (EC) No 178/2002.*

Or. en

#### **Amendment 22**

##### **Proposal for a directive**

##### **Article 3 – title**

*Text proposed by the Commission*

*Amendment*

*Provisional prohibition*

Prohibition

Or. en

#### **Amendment 23**

##### **Proposal for a directive**

##### **Article 3 – paragraph 1 – introductory part**

*Text proposed by the Commission*

*Amendment*

*Member States shall provisionally prohibit:*

*The following shall be prohibited:*

Or. en

## Amendment 24

### Proposal for a directive Article 3 – paragraph 1 – point b

*Text proposed by the Commission*

(b) the placing on the market of animal clones **and** embryo clones.

*Amendment*

(b) the placing on the market **and import** of animal clones, embryo clones, **descendants of animal clones, germinal products of animal clones and of their descendants, and food from animal clones and their descendants.**

Or. en

## Amendment 25

### Proposal for a directive Article 3 – paragraph 1 a (new)

*Text proposed by the Commission*

*Amendment*

***To ensure that no animal clones, descendants of animal clones, germinal products of animal clones and of their descendants and food from animal clones and their descendants are imported into the Union from third countries where they can be legally placed on the market or exported, the Commission shall adopt specific import conditions under Article 48 or Article 49 of Regulation (EC) No 882/2004 of the European Parliament and of the Council<sup>1a</sup> by [date: 6 months after the entry into force of this Regulation].***

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***<sup>1a</sup> Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law,***

**Amendment 26**

**Proposal for a directive  
Article 3 a (new)**

*Text proposed by the Commission*

*Amendment*

*Article 3a*

*Traceability*

*To provide competent authorities and economic operators with the information they need for the application of point (b) of the first paragraph of Article 3, traceability systems shall be established for:*

- (a) animal clones;*
- (b) descendants of animal clones;*
- (c) germinal products of animal clones and of their descendants.*

*The Commission shall be empowered to adopt delegated acts, in accordance with Article 4a, to establish detailed rules for the inclusion of the information referred to in points (a) to (c) of the first subparagraph in the certificates provided for in animal health and zootechnical legislation or in the certificates drawn up by the Commission for those purposes. Those delegated acts shall be adopted by [date: 6 months after the entry into force of this Regulation].*

## Amendment 27

### Proposal for a directive Article 4 – paragraph 1

*Text proposed by the Commission*

Member States shall lay down the rules on penalties applicable to infringements of **the national provisions adopted pursuant to this Directive** and shall take all measures necessary to ensure that they are **implemented**. The penalties provided for **must** be effective, proportionate **and** dissuasive. Member States shall notify those provisions to the Commission by [date **for transposition** of the **Directive**] **at the latest** and shall notify it without delay of any subsequent amendment **affecting them.**'

*Amendment*

Member States shall lay down the rules on penalties applicable to infringements of this **Regulation** and shall take all measures necessary to ensure that they are **applied**. The penalties provided for **shall** be effective, proportionate, dissuasive **and shall ensure a level playing field**. Member States shall notify those provisions to the Commission by [date: **1 year from the entry into force** of the **Regulation**] and shall notify it without delay of any subsequent amendment **thereto**.

Or. en

## Amendment 28

### Proposal for a directive Article 4 a (new)

*Text proposed by the Commission*

*Amendment*

#### *Article 4a*

##### *Exercise of the delegation*

- 1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.*
- 2. The power to adopt delegated acts referred to in Article 3a shall be conferred on the Commission for a period of five years from [date of entry into force of the Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The*

*delegation of power shall be tacitly extended for periods of an identical duration unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*

*3. The delegation of power referred to in Article 3a may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.*

*4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.*

*5. A delegated act adopted pursuant to Article 3a shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.*

Or. en

## **Amendment 29**

### **Proposal for a directive Article 5 – paragraph 1**

*Text proposed by the Commission*

1. By [date = 5 years after the date of **transposition** of this **Directive**], the Member States shall report to the Commission on the experience gained by them on the application of this **Directive**.

*Amendment*

1. By [date: 6 years after the date of **entry into force** of this **Regulation**], the Member States shall report to the Commission on the experience gained by them on the application of this **Regulation**.

Or. en

**Amendment 30**

**Proposal for a directive**

**Article 5 – paragraph 2 – point b a (new)**

*Text proposed by the Commission*

*Amendment*

**(ba) the evolution of consumer perceptions on cloning;**

Or. en

**Amendment 31**

**Proposal for a directive**

**Article 5 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2a. The Commission shall make the report referred to in paragraph 2 publicly available.**

Or. en

## Amendment 32

### Proposal for a directive Article 6

*Text proposed by the Commission*

*Amendment*

#### *Article 6*

*deleted*

#### *Transposition*

*1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [date = 12 month after the date of transposition of this Directive]. They shall forthwith communicate to the Commission the text of those provisions.*

*When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.*

*2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.*

Or. en

## Amendment 33

### Proposal for a directive Article 7 – title

*Text proposed by the Commission*

*Amendment*

*Entering into force*

*Entry into force*

Or. en

**Amendment 34**

**Proposal for a directive  
Article 7 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***It shall apply from [date: 1 year from the entry into force of the Regulation].***

Or. en

**Amendment 35**

**Proposal for a directive  
Article 8**

*Text proposed by the Commission*

*Amendment*

***Article 8***

***deleted***

***Addressees***

***This Directive is addressed to the Member States.***

Or. en

**Amendment 36**

**Proposal for a directive  
Ending part (new)**

*Text proposed by the Commission*

*Amendment*

***This Regulation shall be binding in its entirety and directly applicable in Member States.***

Or. en



## EXPLANATORY STATEMENT

### Background

Cloning is a form of asexual reproduction performed in a laboratory where animals are generated by using the genetic material from a cell from another animal. The animal clone shares the same DNA as its genetic donor. In practice, the main technique used for cloning is “somatic cell nuclear transfer”, where the nucleus of a normal body cell is transferred into an egg (oocyte) from another animal from which the nucleus has been removed; the manipulated oocyte is implanted into a surrogate mother who will - if everything goes well - give birth to the clone.

At present, cloning is not used for farming purposes in the European Union. However, it is used in certain third countries, such as the USA, Canada, Argentina, Brazil and Australia. Cloning may for instance be used to multiply top-performing breeding animals. It may reduce the number of animals required for breeding programmes, as it allows the production of higher quantities of reproductive material with the genes of the elite animals. The high-value reproductive material from clones would then be used to breed animals through conventional reproduction techniques.

Scientific studies have demonstrated with overwhelming evidence that animal cloning is a hazard for animal welfare. The somatic cell nuclear transfer technique leads to placental and foetal abnormalities that result in poor welfare – and often substantial pain – to surrogate dams used for cloning and to their offspring. This naturally also leads to ethical issues related to the justification of the cloning technique.

Cloning is also an issue which is highly sensitive for European citizens: for instance, a Eurobarometer survey of 2010 showed that the European public sees animal cloning as not offering benefits, as unsafe, inequitable and worrying, with only 18% of respondents supporting the technique at all. The European Parliament has had a firm negative stance as regards the cloning of animals for farming purposes. Following up on Parliament’s resolution of 3 September 2008 on the cloning of animals for food supply, the first proposal adopted by Parliament to address the issue of cloning was put forward in the context of the 2008 proposal for a regulation on Novel Foods, and cloning is precisely the issue owing to which the dossier ultimately ended in a deadlock in Conciliation in December 2011. Since then, in several of its adopted positions, the Parliament has consistently strived to introduce into the Union’s legislation specific provisions on cloning to address the citizens’ concerns.

On 18 December 2013, the European Commission published two legislative proposals on the cloning of animals for food supply: the proposal under consideration, and an accompanying proposal for a Council Directive on the placing on the market of food from animal clones (2013/0434(APP)). The proposals suspend the use of the cloning technique in the EU for farm animals, the placing on the market of live animal clones and embryo clones, and the marketing of food, such as meat and milk, from animal clones.

### The Rapporteurs’ position

The Rapporteurs are of the opinion that the negative effects of cloning, inter alia on animal welfare, greatly outweigh any possible positive effects. They therefore welcome the prohibition of the cloning technique put forward by the Commission, but believe that the proposal falls short of properly addressing the valid concerns that have been repeatedly expressed by the citizens and by the European Parliament. In particular, the Commission did not include any specific provisions on food from the descendants of cloned animals, nor any measures as regards the reproductive material from clones and their descendants. The Rapporteurs propose therefore a number of amendments to the Commission proposal, in order to strengthen it and increase its effectiveness, along the following lines.

- ***Descendants and germinal products:*** cloning of animals for farming purposes is not currently taking place in the EU, and in any case the use of the cloning technique is so expensive, and its success rate so low, that its use for food production is not profitable. Hence, the prohibitions proposed by the Commission as regards the placing on the market of live animal clones and the marketing of food from animal clones just enforce the status quo and do not address the main concerns related to cloning, namely the production of *germinal products* (semen, oocytes and embryos) from clones to be used to breed animals (the *descendants* of clones) through conventional reproduction techniques.

The cloning technique is and will remain allowed in certain third countries. It would be incoherent to ban the cloning technique in the EU, on the basis of very significant scientific and ethical grounds, while still allowing imports of the main products for which that technique is mainly used, namely germinal products from clones and food from descendants of clones. In order to ensure the coherence of the legislation it is therefore necessary to also *prohibit the import and the placing on the market of the descendants of animal clones, and of the germinal products and of the food coming from animal clones and their descendants*. That prohibition would also address the worries of consumers as regards the possible long-term effects of the consumption of food (such as meat and milk) from the descendants of animal clones, on which scientific data is still sparse.

To enforce that prohibition, the Commission will have to adopt *specific import conditions* under the “Official controls” Regulation (EC) No 882/2004, before the proposed legislation starts to apply. Moreover, the Rapporteurs consider that *mandatory traceability* is a basic and feasible requirement in this context, as the application of the prohibition would be jeopardised if it is impossible to trace animal clones, their descendants and the corresponding products. The Commission, in its 2010 report on animal cloning for food production, had already promised to establish specific traceability requirements within the zootechnical legislation. While the traceability system would have no direct effect inside the Union, where the use of the cloning technique will be prohibited, live animals, germinal products and food imported into the Union from third countries should be subject to at least equivalent identification conditions and traceability requirements as those applicable in the Union. The Commission will have to adopt, by means of delegated acts prior to the date of application of the legislation, rules for the inclusion of traceability requirements into the certificates provided for in animal health and zootechnical legislation.

The Rapporteurs consider that the legal basis of the proposal, Article 43 of the Treaty on

the Functioning of the European Union, is appropriate for the introduction of the above-described amendments. In fact, according to case-law of the Court of Justice, Article 43 is the appropriate legal basis for any legislation concerning the production and marketing of agricultural products which contributes to the achievement of one or more of the objectives of the common agricultural policy, and can also be used for the adoption of legislation addressing other objectives besides those of the common agricultural policy. Furthermore, measures taken in the context of the common agricultural policy may also affect the import of the products concerned.

- **Scope of the legislation:** although not as substantial as the evidence concerning mammals, there is scientific evidence for poor welfare in dams and offspring due to cloning procedures in farmed fish and related germ cell transplantation procedures in poultry. It is therefore appropriate that the proposed measures apply to *all farmed animals*, and not only to animals of the bovine, porcine, ovine, caprine and equine species as proposed by the Commission.
- **Temporary or permanent prohibition:** the proposal qualifies the prohibitions on the use of cloning as “provisional”, referring to a “suspension” of the use of the technique. However, such a qualification is not justified by any substantive element in the proposed act, and is therefore misleading and should be deleted. Moreover, it has to be kept in mind that the reported frequency of harms to cloned mothers and offspring has shown no substantial improvement for the past decade and that a more efficient methodology for cloning is neither currently available nor seems likely to be developed in the near future. However, the Rapporteurs fully agree with keeping a reporting and review clause, as proposed by the Commission, taking into account all relevant aspects, such as the scientific and technical progress in this area.
- **Choice of legal instrument:** finally, while the Commission considers that a Directive is the most appropriate instrument for this legislation as it would allow Member States to employ existing control tools for the implementation, the core of the proposal is a simple prohibition on the use of cloning and the placing of the market of the corresponding products, and such a prohibition would better be enforced by a *Regulation*. Using a Regulation as the legal instrument would enhance legal certainty and ensure the rationality and consistency of the enforcement, while respecting the subsidiarity and proportionality principles.

In summary, the Rapporteurs believe that the Commission proposal should be strengthened by adopting a more comprehensive approach to all aspects related to the cloning of animals for farming purposes. The amendments proposed in this draft report aim at putting into place an effective and coherent Regulation that addresses the legitimate concerns of the farming sector and of the European citizens at large.